IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
ABERDEEN DIVISION

ROCKY ESTES — PLAINTIFF

V. — CAUSE NO.: 1:14CV052-SA-DAS

LANX, INC., et al. — DEFENDANTS

MEMORANDUM OPINION

The Court entered an Order [110] and Memorandum Opinion [111] granting in part Defendant's Motion for Summary Judgment and dismissing all but one of Plaintiff's claims. An Order to Show Cause was issued on whether the final remaining claim was preempted pursuant to the United States Supreme Court case *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-49, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001). Prior to submitting his supplemental briefing, Plaintiff also filed a Second Motion to Amend/Correct Complaint [113], a Motion to Reopen Discovery [114], and a Motion to Continue Trial [115]. The Court will address the remaining claim, as well as the other pending motions here.

1. Motion to Amend/Correct Complaint

Plaintiff seeks to amend his First Amended Complaint to clarify those claims that the Court noted were not pled in the Memorandum Opinion on summary judgment. The Plaintiff contends failure to warn under the Mississippi Products Liability Act and the negligence for releasing the Telluride Spinal Fixation System into commerce without proper FDA clearance were sufficiently pled and admits that the "amendment does not bring any new issue before the Court and is made to clarify Plaintiff's position."

Federal Rule of Civil Procedure 15(a)(2) provides that leave to amend a pleading should be freely given when justice so requires. However, "[i]t is within the district court's discretion to

deny a motion to amend if it is futile." *Stripling v. Jordan Prods. Co., LLC*, 234 F.3d 863, 872-73 (5th Cir. 2000). "'Futility' in this context . . . mean[s] that the amended complaint would fail to state a claim upon which relief could be granted." *Id.*at 873.

The Court analyzed the merits of Plaintiff's claims, even those claims which were not separately pled, in the Memorandum Opinion. Even considering those claims, the Court found there were no genuine issues of material fact. Thus, amendment of Plaintiff's Complaint would be futile. Accordingly, the Motion to Amend/Correct Complaint [113] is DENIED.

2. Motion to Reopen Discovery

Plaintiff additionally requests the opportunity to reopen discovery in order to take a second deposition of Dr. Glenn Crosby. Plaintiff notes that since September, he has been attempting to get Dr. Crosby to execute an affidavit sent to him to support Plaintiff's failure to warn claim.

Discovery was initially due in this case on December 26, 2014. Plaintiff sought to extend that deadline, and the magistrate judge granted that extension to February 9, 2015, by Order [27]. The discovery deadline was later extended to March 6, then June 9, and finally, August 24. In total, the parties had one full year of discovery, as opposed to the original six months. The Court DENIES the Motion to Reopen Discovery [114].

3. Implied Preemption Doctrine

Plaintiff and Defendant have now both responded to the Court's Order to Show Cause as to why the federal implied preemption doctrine would not apply to Plaintiff's claims regarding the FDA approval process. The implied preemption doctrine is based on the fact that any suit to enforce the Food, Drug, and Cosmetic Act (FDCA) "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Committee,* the Supreme Court

held that claims that "exist solely by virtue" of the federal regulatory scheme—"[s]tate-law fraud-on-the-FDA claims"—are impliedly preempted by federal law because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350, 353, 121 S. Ct. 1012. Thus, "[t]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 700 (S.D. Tex. 2014); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219 (W.D. Okla. 2013) (finding that fraud claims are impliedly preempted by *Buckman* because "even the concept of 'off-label use' is a creature of the FDCA"); *Ledet v. Medtronic, Inc.*, 2013 WL 6858858, at *4–6 (S.D. Miss. Dec. 30, 2013) (dismissing all claims as expressly or impliedly preempted).

As noted by the Court, *Buckman* involved substantially similar facts and legal theories. There, the plaintiffs claimed to have suffered injuries from implantation of orthopedic bone screws into their spines. The plaintiffs alleged that the regulatory consultant to the manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market the screws. *Buckman*, 531 U.S. at 350, 121 S. Ct. 1012. There, as here, the plaintiffs sought to hold the defendant responsible for representations made in a 510(k) to the FDA. The plaintiffs argued that but for this fraud, the FDA would not have approved the screws and the plaintiffs would not have been injured. *Id.* at 347, 121 S. Ct. 1012. The Supreme Court titled the claim asserted in *Buckman* was a state law "fraud-on-the-FDA" claim in which fraudulent misrepresentations were allegedly made during an FDA approval process. As noted by another court, the fraudulent actions for which the *Buckman* plaintiffs sought recovery would not have occurred in a world

without the FDCA. *Schouest*, 13 F. Supp. 3d at 704. Indeed, the reason the plaintiffs found the manufacturer's conduct so objectionable was that, in his view, the FDA would not have approved the device if not for the misrepresentations made during the preapproval process. *See id.* Thus, *Buckman* has been interpreted to preempt claims that are based on conduct that could not have occurred in the absence of the FDCA regulatory scheme. *See Buckman*, 531 U.S. at 353, 121 S. Ct. 1012 (noting that the claims at issue "exist[ed] solely by virtue of the FDCA disclosure requirements"); *Caplinger*, 921 F. Supp. 2d at 1215 (finding claims impliedly preempted where liability premised on conduct that violates the FDCA); *but see Hughes v. Boston Scientific Corp.*, 631 F. 3d 762, 775 (5th Cir. 2011) (overturning dismissal on the basis of preemption where Mississippi tort claim based on underlying state duty to warn about the dangers or risks of product).

Plaintiff's claims here are premised on Lanx's failure to submit a standalone 510(k) premarket notification on the Lanx Telluride Spinal Fixation System. Estes contends that the Telluride Spinal Fixation System should not have been available for use because it was not cleared by the FDA, and that Lanx was negligent in releasing the system without proper FDA clearance or fraudulently concealed that fact. In fact, Estes contends that Lanx "denied the FDA its mandated obligation to review a 510(k)" in order to determine if the Telluride System was safe, effective, and reliable. *See* Response [99], p.20. Accordingly, Plaintiff's fraud claim is based and premised on Lanx's alleged violation of the FDCA. Plaintiff's fraud claim solely arises out of the alleged violation of the FDCA, not state substantive law. Thus, Plaintiff's claims are preempted.

Defendant's Motion for Summary Judgment [94] is GRANTED, Plaintiff's remaining claims are DISMISSED, and this case is CLOSED. All other pending motions are dismissed without prejudice.

SO ORDERED, this the 14th day of January, 2016.

/s/ Sharion Aycock
U.S. DISTRICT JUDGE